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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,129	04/11/2005	Satoshi Saito	03419.0023-00	8898

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EXAMINER	
LONG, SCOTT	

ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,129	SAITO ET AL.	
	Examiner	Art Unit	
	SCOTT LONG	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,16-18,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *4,5,20 and 21* is/are allowed.

6)☒ Claim(s) *1-3,6,7 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of Applicant's Remarks and Claim amendments, filed on 4 August 2010.

Claim Status

Claims 1-7, 16-18 and 20-21 are pending. Claim 8-15 and 19 are cancelled. Claims 1, 4 and 16 are amended.

Priority

This application claims benefit as a 371 of PCT/JP03/02833 0 (filed 3/11/2003). This application also claims benefit from the foreign application JAPAN 2002-065880 (filed 03/11/2002). Therefore, the instant application has been granted the benefit date, 3/11/2002, from the foreign application JAPAN 2002-065880.

RESPONSE TO ARGUMENTS

35 USC § 112, 2nd

The rejection of claim 1-3, 6-7 and 16-18 are rejected under 35 U.S.C. 112, second paragraph, is withdrawn in response to the applicant's claim amendments. The applicant has amended instant claims 1 and 16 to recite , "lactate dehydrogenase gene coding sequence." This language provides sufficient clarity to the claim to overcome the examiner's assertion of indefiniteness.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 6-7 and 16-18 remain rejected under 35 U.S.C. 103(a) as being obvious over Porro et al. (WO99/14335) for the reasons of record and the comments below.

The applicant has amended the instant claims to clarify the instant claims.

The applicant's arguments have been fully considered and but are unpersuasive.

The applicant argues “the claimed transformants provide unexpected benefits over the teachings of Porro…[and] were not predictable in the prior art” (Remarks, page 9, filed 8/4/2010, parag.1). The applicant further “submits that the expression ‘an increased efficiency’ presented in the Applicant’s argument and Declaration does not correspond to the term ‘fermentation efficiency’ as relied on in the Office Action [mailed 5/7/2010]” (Remarks, filed 8/4/2010, page 9, parag.3). The applicant further indicates that in “the Declaration, Applicant argued that the claimed transformant produced unexpectedly large amount of lactic acid, as compared to the prior art.” (Remarks, page

10, 1st parag., emphasis added by applicant). The applicant has attempted to dismiss the examiner's arguments which provided an art recognized definition of "fermentation efficiency" by stating that this meaning is not the applicant's preferred meaning of the phrase 'an increased efficiency.' However, the phrase, "increased efficiency" is not defined in the specification. As mentioned in previous Actions, the repetitive use of the phrase "increased efficiency" without a positive statement as to its meaning will be insufficient to overcome the pending rejection. The applicant's statement that he wishes the phrase "increased efficiency" to mean something other than an art recognized meaning, will also be insufficient to overcome the pending rejection without a positive statement as to what this term actually means. Accordingly, the examiner finds the applicant's arguments unpersuasive.

The applicant has directed his arguments to an "unexpectedly large amount of lactic acid" and "higher lactic acid yield" (Remarks, page 10, parag.1). As discussed in the Office Action, filed 5/7/2010, Table 1 of the Declaration shows the present application produces 32.8% lactic acid yield, while Porro (WO99/14335) produces 33.8% lactic acid yield; the yields of these systems are nearly identical. On its surface, this comparison does not seem to suggest any unexpected characteristic of the claimed invention. Accordingly, the examiner finds the applicant's arguments unpersuasive.

The applicant provides his own logic to surmise that the lactic acid yield predicted by Porro would be 1.7% (Remarks, pages 9-10). The applicant's logic is based upon an assumption that the production of lactic acid is due solely to the copy number of genes present in each transformant. The examiner has previously presented (Action, filed

5/7/2010) his reasoning why there may be a variety of factors (other than lactic acid gene copy number) which can influence the lactic acid yield of produced by a microorganism in media. These factors include: (1) strain of *S. cerevisiae* used and (2) medium used in a particular fermentation process. The data presented in the Onishi Declaration (filed 23 March 2010) fail to definitively elucidate the copy number of genes as being the sole factor influencing production of lactic acid. Therefore, the examiner cannot conclude that the claimed transformant is non-obvious over the transformant of Porro. Accordingly, the examiner finds the applicant's arguments unpersuasive.

Based upon the applicant's reasoning that the predicted yield of Porro is ~1.7%, the applicant makes the case that the "lactic acid yield disclosed in Ishida (62.2%) and the yield disclosed in the present application (32.8%) do not differ as compared to the difference in lactic acid yields between the present application and the yield predicted in Porro (~1.7%). The examiner notes that the applicant conjectures the yield of Porro to be ~1.7%, while the Onishi Declaration (filed 23 March 2010, Table 1) indicates that the actual yield of Porro is 33.8%. Therefore, using the logic of relative comparisons as suggested by the applicant's arguments, the lactic acid yield of Porro's transformants (33.8%) and the lactic acid yield of the claimed transformants (32.8%) have less difference than a comparison between the lactic acid yield disclosed in Ishida (62.2%) and the yield disclosed in the present application (32.8%). Accordingly, the examiner finds the applicant's arguments unpersuasive.

The applicant further argues that Porro does "not disclose at least 'wherein the pyruvate decarboxylase gene on the host chromosome is replaced with the single copy

of the lactate dehydrogenase gene [incorporated into the host chromosome],' as presently claimed" (Remarks, page 12, parag.2). In the pending rejection, the examiner has acknowledged that "Porro et al. does not teach knocking out the host genome's pyruvate decarboxylase gene, by introducing a gene expression cassette in its place." However, in the pending rejection, the examiner provides a scientific rationale for satisfying this claim limitation:

> Regarding eliminating the host genome's pyruvate decarboxylase gene by replacing it with a DNA cassette which includes "a DNA for coding a foreign protein having lactate dehydrogenase activity operably linked to a functional homologue of the genome promoter of the pyruvate decarboxylase gene," it would have been obvious because of a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and commonsense. The prior art teaches the need in the art to solve the problem of optimally producing a recombinant microorganism which has been knocked out for a pyruvate decarboxylase gene and further identifies a number of predictable potential solutions for making these deletions/ knockouts (by deletion of the gene; deletion or insertion of selectable markers, point-mutations, frame-shift mutations (Porro, page 10, lines 9-24)). One of ordinary skill in the art could have pursued the known potential option (of inserting the DNA cassette comprising pyruvate decarboxylase promoter/exogenous lactate dehydrogenase gene) with a reasonable expectation of success. It would be therefore predictably obvious to use an alternative method when eliminating the host genome's pyruvate decarboxylase gene.

As the examiner has provided a reasonable basis for a skilled artisan in possession of Porro et al. to practice the disputed claim limitation directed to "wherein the pyruvate decarboxylase gene on the host chromosome is replaced with the single copy of the lactate dehydrogenase gene [incorporated into the host chromosome]," the examiner finds the applicant's argument unpersuasive.

Accordingly, the examiner hereby maintains the rejection of claims 1-3, 6-7 and 16-18 under 35 U.S.C. 103(a) as being obvious over Porro et al.

The examiner reiterates the pending rejection:

Claims 1-3, 6-7 and 16-18 are rejected under 35 U.S.C. 103(a) as being obvious over Porro et al. (WO99/14335).

Claim 1 is directed to a bacterial or yeast transformant into which has been incorporated a lactate dehydrogenase gene, there the lactate dehydrogenase gene encodes for a foreign protein having lactate dehydrogenase activity and provided with pyruvic acid substrate affinity that equals or exceeds the pyruvic acid substrate affinity of the pyruvate decarboxylase inherent in the host organism, wherein a single copy of the lactate dehydrogenase gene has been incorporated such that it is under the control of a genomic pyruvate decarboxylase gene promoter on the host chromosome, or such that it is under the control of a structural and functional homologue of the genomic pyruvate decarboxylase gene promoter, which replaces the genomic pyruvate decarboxylase gene promoter on the host chromosome, and wherein the pyruvate decarboxylase gene on the host chromosome is replaced with the single copy of the lactate dehydrogenase gene. Porro et al. teach, “yeast strains…transformed with at least one copy of a gene coding for lactic dehydrogenase (LDH) functionally linked to promoter sequences allowing the expression of said gene in yeasts” (page 4, lines 6-11). Porro et al. teach, “yeast strains having…a reduced pyruvate decarboxylase activity and transformed with…a gene coding for lactic dehydrogenase (LDH) functionally linked to promoter sequences” (page 4, lines 12-17). Porro et al. teach any

yeast promoter…may be used according to the invention…the promoter of pyruvate decarboxylase gene of K. lactis (KlPDC) is particularly preferred (page 14, lines 18-28). Porro et al. further teach, "Pyruvate decarboxylase gene promoters…are particularly preferred" (page 15, lines 2-5). Porro et al. describe making a triple deletion of the pyruvate decarboxylase genes encoding PDC1, PDC5, and PDC6, using homologous recombination (page 8, lines 25-27). Porro et al. further teach that "PDC genes are highly conserved among different yeast genera" (page 9, lines 7-9). Porro et al. also teach "integrative vectors can be obtained by using homologous DNA sequences in certain regions of the host genome, allowing, by homologous recombination, integration of the vector" (page 12, lines 12-15).

Claim 2 is directed to the transformant according to claim 1, wherein the foreign protein is a bovine-derived lactate dehydrogenase or its homologue. Porro et al. teach, "the gene coding for lactate dehydrogenase may be of any species (e.g. mammalian, such as bovine)" (page 9, lines 29-30).

Claim 3 is directed to the transformant according to claim 1, wherein the foreign protein is a protein comprised of the amino acid sequence shown in sequence number 1 or its homologue. SEQ ID NO:1 is the bovine lactate dehydrogenase gene. Clearly, Porro et al. contemplates the amino acid encoded this gene or its homologue. Porro et al. teach, "the gene coding for lactate dehydrogenase may be of any species (e.g. mammalian, such as bovine)" (page 9, lines 29-30). Furthermore, Porro et al. explicitly claims a transformed yeast comprising a bovine lactate dehydrogenase gene (page 65, claim 17).

Claim 6 is directed to the transformant according to any of claims 1 through 5, wherein the host organism belongs to the Saccharomyces family.

Claim 7 is directed to the transformant according to any of claim 1, wherein the host organism is Saccharomyces cerevisiae. Porro et al. teach transformed yeast, Saccharomyces cerevisiae.

Claim 16 is directed to a transformant of the Saccharomyces family into which a single copy of a lactate dehydrogenase gene, wherein the lactate dehydrogenase gene encodes a bovine-derived lactate dehydrogenase or its homologue and has been incorporated such that the lactate dehydrogenase gene is under the control of a genomic pyruvate decarboxylase 1 gene promoter on the host chromosome of the Saccharomyces family or such that the lactate dehydrogenase gene is under the control of a structural and functional homologue of the genomic pyruvate decarboxylase 1 gene promoter, which replaces the genomic pyruvate decarboxylase 1 gene promoter, and wherein the pyruvate decarboxylase 1 on the host chromosome has been replaced with a single copy of the lactate dehydrogenase gene encoding the bovine-derived lactate dehydrogenase or its homologue. Porro et al. teach, "yeast strains…transformed with at least one copy of a gene coding for lactic dehydrogenase (LDH) functionally linked to promoter sequences allowing the expression of said gene in yeasts" (page 4, lines 6-11). Porro et al. teach, "yeast strains having…a reduced pyruvate decarboxylase activity and transformed with…a gene coding for lactic dehydrogenase (LDH) functionally linked to promoter sequences" (page 4, lines 12-17). Porro et al. teach any yeast promoter…may be used according to the invention…the

promoter of pyruvate decarboxylase gene of K. lactis (KlPDC) is particularly preferred (page 14, lines 18-28). Porro et al. further teach, "Pyruvate decarboxylase gene promoters…are particularly preferred" (page 15, lines 2-5). Porro et al. describe making a triple deletion of the pyruvate decarboxylase genes encoding PDC1, PDC5, and PDC6, using homologous recombination (page 8, lines 25-27). Porro et al. further teach that "PDC genes are highly conserved among different yeast genera" (page 9, lines 7-9). Porro et al. also teach "integrative vectors can be obtained by using homologous DNA sequences in certain regions of the host genome, allowing, by homologous recombination, integration of the vector" (page 12, lines 12-15).

Claim 17 is directed to the transformant according to claim 16, wherein the host is Saccharomyces cerevisiae. Porro et al. teach transformed yeast, Saccharomyces cerevisiae.

Claim 18 is directed to a lactic acid manufacturing method provided with a process for culturing the transformant described in claim 1, and a process for separating lactic acid from the cultured product obtained in said process for culturing the transformant. Porro et al. teach, "a process for the preparation of…lactic acid by culturing the above described metabolically engineered yeast strains in a fermentation medium containing a carbon source and recovering lactic acid from the fermentation medium" (page 5, lines 5-10).

Porro et al does not explicitly teach a single embodiment of a transformed bacteria or yeast comprising a DNA for coding a foreign protein having lactate dehydrogenase activity operably linked to a functional homologue of the genome

promoter of the pyruvate decarboxylase gene and in which the DNA has been homologously recombined to eliminate the host genome's pyruvate decarboxylase gene. However, Porro et al. teaches all of the structural elements (transformed yeast and bacteria; introduction of a foreign (bovine) lactate dehydrogenase gene; using a pyruvate decarboxylase promoter for expression of exogenous protein expression; and homologous recombination; knocking out the host genome's pyruvate decarboxylase gene). However, Porro et al. does not teach knocking out the host genome's pyruvate decarboxylase gene, by introducing a gene expression cassette in its place.

It would have been obvious to the person of ordinary skill in the art at the time of the invention was made to make a single embodiment of a transformed bacteria or yeast comprising a DNA for coding a foreign protein having lactate dehydrogenase activity operably linked to a functional homologue of the genome promoter of the pyruvate decarboxylase gene and in which the DNA has been homologously recombined to eliminate the host genome's pyruvate decarboxylase gene.

Regarding the rationale for combining prior art elements according to known methods to yield predictable results, all of the claimed elements were known in the prior art and one skilled in the art could have combined the element as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Each of the elements (transformed yeast and bacteria; introduction of a foreign (bovine) lactate dehydrogenase gene; using a pyruvate decarboxylase promoter for expression of exogenous protein expression; homologous recombination; knocking out the host

genome's pyruvate decarboxylase gene) are taught by Porro et al. and further they are shown to be used for the production of lactic acid. It would be therefore predictably obvious to use a combination of these elements in a recombinant bacteria or yeast.

In addition, Porro et al. also teach "integrative vectors can be obtained by using homologous DNA sequences in certain regions of the host genome, allowing, by homologous recombination, integration of the vector" (page 12, lines 12-15). A skilled artisan would be guided by the suggestion of Porro to generate a transgenic bacteria or yeast having lactate dehydrogenase integrated into the genome because in his teachings, Porro suggests using vectors capable of homologous recombination to introduce the foreign (bovine) lactate dehydrogenase into the microorganism.

Regarding eliminating the host genome's pyruvate decarboxylase gene by replacing it with a DNA cassette which includes "a DNA for coding a foreign protein having lactate dehydrogenase activity operably linked to a functional homologue of the genome promoter of the pyruvate decarboxylase gene," it would have been obvious because of a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and commonsense. The prior art teaches the need in the art to solve the problem of optimally producing a recombinant microorganism which has been knocked out for a pyruvate decarboxylase gene and further identifies a number of predictable potential solutions for making these deletions/ knockouts (by deletion of the gene; deletion or insertion of selectable markers, point-mutations, frame-shift mutations (Porro, page 10, lines 9-24)). One of ordinary skill in

the art could have pursued the known potential option (of inserting the DNA cassette comprising pyruvate decarboxylase promoter/exogenous lactate dehydrogenase gene) with a reasonable expectation of success. It would be therefore predictably obvious to use a alternative method when eliminating the host genome's pyruvate decarboxylase gene.

Furthermore, codon optimization of the bovine lactate dehydrogenase gene for expression in Saccharomyces cerevisiae is well known in the art and therefore obvious.

Therefore the recombinant bacteria or yeast as taught by Porro et al would have been *prima facie* obvious over the recombinant bacteria or yeast of the instant application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

This is a provisional obviousness-type double patenting rejection.

Claim 1-7 and 16-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-28 of copending Application No. 12/324804 (US2009/0275095).

Instant claims 4-5 recite polynucleotide sequences (SEQ ID NOs:3-4) encoding bovine lactate dehydrogenase which has been codon optimized for expression in Saccharomyces cerevisiae. Claims 16-17 of Application No. 12/324804 recite the same sequences. The claims of copending Application No. 12/324804 encompass the instant claims because they are both directed to transgenic yeast comprising bovine LDH operatively linked to pyruvate decarboxylase promoter. Further they both claim methods of making lactic acid using these recombinant yeasts.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Claims 4-5 and 20-21 are allowed. Claims 1-3, 6-7 and 16-18 are rejected.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SCOTT LONG/
Primary Examiner, Art Unit 1633